

We Claim:

1. A method of adjusting an insulin dosing schedule involving the combination of a base insulin dosage administered over a given time interval (Basal Insulin) coupled with an additional insulin dosage administered in relation to a meal taken during the given time interval (Meal Insulin) comprising estimating a desired change in the Meal Insulin and then determining a change in the Basal Insulin from the difference between the change in the total insulin prescribed for the given time interval (Prescription Insulin) less the estimated change in the Meal Insulin, in relation to the insulin dosages given during the same time interval for a previous day.
2. The method of claim 1, wherein the determined change in the Basal Insulin is divided by the elapsed time for the given time interval to obtain a change in the rate at which Basal Insulin is administered (Basal Rate), and then adding the change in the Basal Rate with the Basal Rate during the same time interval for a previous day to obtain a new dosage of Basal Insulin to be administered over the given time interval.
3. The method of claim 1, wherein the estimated desired change in the Meal Insulin is determined as a share of the total cumulative change in Meal Insulin for a given day over a plurality of time intervals in the same proportion as the ratio of the Meal Insulin to the total of all Meal Insulin dosages for the day.
4. The method of claim 1, wherein the estimated desired change in the Meal Insulin is determined as a share of the total cumulative change in Meal Insulin for a given day in the same proportion as the ratio of the grams of carbohydrates ingested during the given time interval to the total grams of carbohydrates ingested over an entire day.
5. The method of claim 1, wherein the estimated desired change in the Meal Insulin is determined from the formula:

(grams of carbohydrates ingested during current time interval)/(carbohydrate-to-insulin ratio for the current time interval) minus (grams of carbohydrates ingested during current time interval)/(carbohydrate-to-insulin ratio for the same time interval for a prior day).

5

6. The method of claim 5, wherein the estimated desired change in the Meal Insulin is determined from a ratio of grams of carbohydrates to the dosage of insulin administered during a different time interval.

10 7. The method of claim 6, wherein the grams of carbohydrates ingested during the current time interval are determined as the carbohydrate-to-insulin ratio multiplied times the Meal Insulin for the given time interval.

15 8. A method of adjusting an insulin dosing schedule involving the combination of a base insulin administered over a given time interval (Basal Insulin) coupled with an additional insulin dosage administered in relation to a meal taken during the given time interval (Meal Insulin) comprising estimating a desired change in the Basal Insulin and then determining the difference between the change in total insulin prescribed for the given time interval (Prescribed Insulin) and the estimated desired change in the Basal Insulin
20 for the given time interval.

9. The method of claim 8, wherein the estimated desired change in the Basal Insulin is determined from the Basal Insulin for the same time interval on a different day.

25 10. The method of claim 8, wherein the estimated desired change in the Basal Insulin is determined from an average of Basal Insulin administered during the same time interval on a plurality of different days.

11. The method of claims 9 and 10, wherein a conversion factor is applied to the Basal Insulin taken during the same time interval on one or more different days, the conversion factor being a statistically determined correlation between the Basal Insulin for the current time interval and that of a time interval for a previous day or days.

5

12. The method of claim 11, wherein the statistical correlation is taken from the patient's own past data.

10 13. The method of claim 11, wherein the statistical correlation is taken from a sampling of a plurality of patients.

14. The method of claim 8, wherein the change to the Basal Rate for the time interval is determined by the method of claim 16 and multiplied by the elapsed time over the time interval to obtain the change in the Basal Insulin.

15

15. The method of claim 8, wherein the change in the desired Basal Insulin is determined employing the method of claim 1.

16. A method of adjusting an insulin dosing schedule involving the combination of a
20 base insulin dosage administered over a given time interval (Basal Insulin) coupled with an additional insulin dosage administered in relation to a meal taken during the given time interval (Meal Insulin) comprising a time interval that starts near the end of a meal, and in which an after meal insulin bolus is administered intermediate between the start and the end of the given time interval, and in which a change to the Basal Insulin for the
25 time interval is determined based on a later portion of the time interval, the change in the Basal Insulin being used to determine a change in the Basal Insulin for an earlier portion of the time interval which is subtracted from a desired change in the prescribed insulin dosage to obtain a change in the Meal Insulin for the given time interval.

17. The method of claim 16, wherein the change to the Basal Insulin in the later portion of the time interval is a predetermined fraction of a corrective insulin dosage at the end of the time interval.
- 5 18. The method of claim 17, including dividing the change to the Basal Insulin for the later portion of the time interval by the elapsed time over the time interval to obtain a Basal Rate for the entire time interval.
19. The method of claim 16, wherein the change in the prescribed insulin dosage for the
10 earlier portion of the time interval is a predetermined fraction of a corrective insulin dosage intermediate in the time interval after the meal.
20. The method of claim 19, wherein the predetermined fraction is the same as that of claim 17.
- 15 21. The method of claim 20, wherein the predetermined fraction is equal to the change in the total day's prescribed insulin divided by the total day's corrective insulin.
22. The method of claims 1, 8, and 16, further including converting the change in Meal
20 Insulin to a new Meal Insulin dosage by adding the change in Meal Insulin to the previously determined Meal Insulin dosage for the given time interval of the immediately previous day.
23. The method of claim 1, further including determining a new carbohydrate-to-insulin
25 ratio by dividing the grams of carbohydrates ingested during the time interval by the new Meal Insulin for the given time interval.

24. The method of claim 23, wherein the grams of carbohydrates ingested are determined by multiplying a carbohydrate-to-insulin ratio by a Meal Insulin dosage for the given time interval of a previous day.
- 5 25. The method of claim 23, wherein the given time interval constitutes a whole day.
26. The method of claim 23, wherein the given time interval constitutes a time interval amounting to less than a whole day.
- 10 27. The method of converting a change in an insulin dosage administered in relation to a meal taken during a given time interval (Meal Insulin) to a change in carbohydrate-to-insulin ratio by taking the calculus derivative of carbohydrate-to-insulin ratio with respect to Meal Insulin for a given time interval.
- 15 28. The method of claim 27, including calculating said derivative as the negative of the grams of carbohydrates ingested during a given time interval divided by the square of the Meal Insulin.
- 20 29. The method of claim 28, including calculating the grams of carbohydrates ingested during a given time interval as the carbohydrate-to-insulin ratio times Meal Insulin for the given time interval.
30. The method of claim 30, including estimating the carbohydrate-to-insulin ratio based on a statistical correlation of carbohydrate-to-insulin ratio to body weight or to the total daily dose of insulin.
- 25 31. The method of claim 30, including estimating the Meal Insulin as a pre-set fraction of the total daily dose of insulin.

32. The method of claim 31, wherein the pre-set fraction is one-half.
33. The method of claim 1, wherein the sum of Meal Insulin and a corrective after-meal insulin dosage is used in place of Meal Insulin.
- 5 34. The method of claim 1, wherein a feedback mechanism is used to regulate the relative proportions of the day's totals of Basal Insulin and Meal Insulin as part of the Prescription Insulin.
- 10 35. The method of claim 34, wherein the feedback mechanism is a factor representing the day's change in Basal Insulin divided by the day's change in Prescription Insulin.
36. The method of claim 35, wherein the feedback factor is calculated as:
$$\text{BoTFbk}(d) = \text{BoT}(d) + \text{Kfbk} * (\text{BoTTgt} - \text{BoT}(d)) * \text{sign}(\text{deRxInsl})$$
- 15 37. The methods of claims 1, 8, and 16, wherein the data for determining the values is data taken from the corresponding time interval for the previous day.
38. The methods of claims 1, 8, and 16, wherein the data for determining the values is
20 data taken from the corresponding time interval for a plurality of days and averaged.
39. The method of claim 1, including calculating a corrective insulin dosage for the given time interval based on the difference of averaged blood glucose measurements taken at or near a specified time over a plurality of days and a target blood glucose level
25 divided by a correction factor.
40. The method of claim 39, wherein the change to Prescription Insulin is determined as a number less the corrective insulin dosage for the time interval.

41. The method of claim 40, wherein the change to Prescription Insulin is a fraction of the corrective insulin for the given time interval equal to a multiplying factor times the corrective insulin for the time interval.
- 5 42. The method of claim 41, wherein the multiplying factor is a number that provides a response time for decreasing the amount of correction over a selected period of time for the correction.
43. The method of claim 42, wherein the multiplying factor is determined as:
- 10 one minus (the remaining percent of original error allowed at the end of the response time) raised to the power (one divided by the number of days in the response time).
44. The method of claim 40, wherein the value of the change in total day's Prescription Insulin is divided by the total day's corrective insulin to obtain the multiplying factor.
- 15 45. (omitted)
46. The method of claim 44, wherein the change to Prescription Insulin applied is limited to a maximum change value based on a set fraction of the sum of the day's total
- 20 corrective insulin.
47. The method of claim 40, wherein the change to Prescription Insulin is limited to a maximum change value based on a set fraction of the corrective insulin determined at the end of a given time interval.
- 25 48. The method of claim 44, wherein the change to Prescription Insulin is automatically adjusted based on a percent standard deviation of a patient's blood glucose in a recent calendar period compared to the mean percent standard deviation of a population sample, and wherein if the patient's standard deviation is high relative to the mean standard

deviation of the population sample, then less change in the Prescription Insulin is employed than the change determined.

49. The method of claim 48, wherein the change in Prescription Insulin equals a fraction
5 multiplier times the maximum change determined.

50. The method of claim 49, wherein the multiplier is determined as follows: if the patient's percent standard deviation of blood glucose measurements is less than the mean of the population of the population percent standard deviations plus one standard
10 deviation of the population percent standard deviations, then the value of the multiplier is one; if the patient's percent standard deviation of blood glucose measurements is between one and two percent standard deviations of the population standard deviation greater than the mean of the population percent standard deviation, then the multiplier is set to ramp linearly downwardly until it reaches zero at the upper bound of this interval; and if the
15 patient's standard deviation of blood glucose measurements is greater than this, then the multiplier is set to zero, allowing no change in Prescription Insulin.

51. The method of automatically estimating a change in the total day's base insulin dosage based on the absolute value of the minimum of the absolute values of the change
20 in the total day's prescribed insulin dosage and a target base insulin dosage less the current base insulin dosage for a time interval shorter than a total day.

52. The method of Claim 36 wherein the target ratio of Basal Insulin over Total Insulin is determined as: one minus the quantity total grams of carbohydrates ingested over a day
25 times an Average Glycemic Index divided by the result of any known statistically-based formula for daily energy requirements of a patient, given the patient's body measurements or other parameters.

53. The method of Claim 36 wherein the AIM Corellation may be used as the target ratio of Basal Insulin over Basal-over-Total Insulin.

54. The method of Claim 51 wherein the estimation of the change in Basal Insulin is converted into an automatic value of change in Meal Insulin by subtracting the change in Basal Insulin from change to total day's Prescription Insulin.

55. The method of Claim 54 wherein the estimation of change to Meal Insulin is multiplied by a fractional reduction factor if the change is in the positive direction.

56. The method of Claim 1 further including a skipped corrective insulin bolus at a time boundary determined based on the sum of insulin boluses from time intervals on either side of a skipped blood glucose measurement corresponding to the skipped corrective insulin bolus.

57. The method of Claims 1, 8, and 16, further including the determination of an insulin bolus based on the amount of exercise for the given time interval.

58. The method of Claims 1,8, and 16, further including the determination of an insulin bolus based on the amount of exercise for the given period of time resulting in a negative insulin dosage suspending the Basal Rate infusion for the appropriate amount of time.

59. The method of Claim 38 wherein a Large Domain formula is employed to distribute the day's change in Prescription Insulin among various time intervals when the Total Corrective Insulin divided by the un-modified Change to Prescription Insulin is less than one.

60. The method of Claim 59 wherein the Large Domain Formula determines the Change in Prescription Insulin within an interval or sub-interval as follows: giving to each

interval the full amount of the Corrective Insulin calculated based on a blood glucose measurement at the end of the interval, then distributing the difference between a desired change in the day's total Prescription Insulin and the day's total Corrective Insulin among the intervals in proportion to each interval's share of the quantity of old Basal Insulin plus
5 Corrective Insulin.

61. The method of Claim 60 wherein, within an interval or sub-interval, the Large Domain Formula for determining change in Prescription Insulin is equal to the Corrective Insulin interval to be administered at the end of the time interval plus the quantity (total
10 change in Prescription Insulin minus the total Corrective Insulin) times the quantity (Basal Insulin for the time interval plus the Corrective Insulin to be administered at the end of the time interval) divided by the quantity (Total Corrective Insulin plus total day's Basal Insulin).

15 62. The method of Claim 61 wherein the formula is implemented by use of a switching parameter as follows: change in Prescription Insulin for the given time interval equals the switching parameter times the Large Domain Formula plus the quantity (one minus the switching parameter) times a Small Domain Formula.

20 63. The method of Claim 62 wherein the value of the switching parameter is one if the day's total Corrective Insulin to be administered at the end of the time intervals for a day divided by the day's change in Prescription Insulin is greater than one, and has the value of zero otherwise.

25 64. The method of Claim 59 wherein two Large Domain Formulas are used, one for a first part of the time interval and one for a latter part of the interval.

65. The method of Claim 64 wherein the Large Domain Formula for the first part of the time interval is calculated as: the change in Prescription Insulin for the first part of the

time interval is equal to an After-Meal Corrective Insulin for the interval plus the quantity (the day's change in Prescription Insulin minus the day's total After-Meal Corrective Insulin minus the day's total of the Corrective Insulin to be administered at the end of the time intervals for the day) times the quantity (the After-Meal Corrective Insulin for the interval plus the Basal Insulin in the interval) divided by the quantity (the day's total After-Meal Corrective Insulin plus the day's total of the Corrective Insulin to be administered at the end of the time intervals for the day plus the day's total Basal Insulin).

66. The method of Claim 64 wherein the Large Domain Formula for the last part of the interval is calculated as: the change in Prescription Insulin for the last part of the time interval is equal to the Corrective Insulin to be administered at the end of the time interval plus the quantity (the day's change in Prescription Insulin minus the day's total After-Meal Corrective Insulin minus the total of the Corrective Insulin to be administered at the end of the time intervals for the day) times the quantity (the Corrective Insulin plus the Basal Insulin in the interval) divided by the quantity (the day's total After-Meal Corrective Insulin plus the day's total of Corrective Insulin plus the total day's Basal Insulin).

67. The method of Claim 64 wherein a switching parameter is used for both parts of the time interval and the value of the switching parameter is one if the ratio of (day's Total After-Meal Corrective Insulin plus Corrective Insulin to be administered at the end of the time interval) divided by (the day's change in Prescription Insulin) is greater than one, and has the value of zero otherwise.

68. The method of claim 37 wherein the program is installed in an insulin pump.

69. The method of claim 37 wherein the program is installed in a kit comprising a blood glucose measuring device, an insulin delivery device, and a microprocessor, one of which being able to store data.

70. The method of claim 69 wherein the microprocessor is within the blood glucose measuring device.

5 71. The method of claim 69 wherein the microprocessor is within the insulin delivery device.

72. The method of claim 69 wherein the microprocessor is separately housed.

10 73. The method of Claim 38 wherein the program is used with pump patients.

74. The method of Claim 38 wherein the program is used with Multiple Daily Injection or Inhaled Insulin.

15 75. The method wherein one of the several algorithms described herein is applied to a time interval depending on the characteristics of the time interval.

76. The method of Claim 75 wherein each time interval is digitally flagged with an "interval-type" parameter as a cue to apply a certain type of dosing algorithm.

20

77. The method of Claim 75 wherein time intervals containing meals are identified.

78. The method of Claim 75 wherein time intervals containing occasional small snacks are identified.

25

79. The method of Claim 75 wherein a time interval is identified as the source of Basal Rate for use in determining insulin dosing during another time interval.

80. The method of Claim 75 wherein a time interval is identified as the source of Carbohydrate-to-Insulin Ratio for use in determining insulin dosing during another time interval.
- 5 81. The method of Claim 75 wherein time intervals containing After-Meal Corrective Insulin are identified by the presence of the After-Meal Corrective Insulin.
82. The method of Claim 75 wherein intervals with missing values of Corrective Insulin to be administered at the end of the time interval are identified by the absence of the
- 10 Corrective Insulin.
83. The method of Claim 75 wherein the version taking data from the corresponding time interval for the previous day employs automatic daily update for Pumps and selects the appropriate algorithm for each time interval and each time interval represents either a
- 15 single time interval from a previous day, or corresponding time intervals taken from a plurality of days and averaged.
84. The method of Claims 83 and 5 wherein the algorithm described in claim 4 is applied to time intervals containing small snacks.
- 20
85. The method of Claims 83 and 8 wherein the algorithm described in claim 8 is applied to time intervals containing meals.
86. The method of Claims 83 and 5 wherein the algorithm described in claim 4 is applied
- 25 to time intervals designated as the source of Basal Rate for use in determining insulin dosing during another time interval.

87. The method of Claims 83 and 8 wherein the algorithm described in Claim 8 is applied to time intervals designated as the source of Carbohydrate-to-Insulin Ratio for use in determining insulin dosing during another time interval.
- 5 88. The method of Claims 83 and 16 wherein the algorithm described in claim 16 is applied to time intervals containing After-Meal Corrective Insulin.
89. The method of Claim 75, wherein the version taking data from the corresponding time interval for the previous day employs automatic daily update for Multiple Daily
10 Injection and Inhaled Insulin and applies the appropriate algorithm to each interval.
90. The method of Claims 89 and 5 wherein the method described in claim 5 is applied to intervals containing small snacks.
- 15 91. The method of Claims 89 and 8 wherein the method described in Claim 8 is applied to intervals containing meals.
92. The method of Claims 89 and 5 wherein the method described in claim 5 is applied to time intervals designated as the source of Basal Rate for use in determining insulin
20 dosing during another time interval.
93. The method of Claims 89 and 8 wherein the method described in Claim 8 is applied to time intervals designated as the source of Carbohydrate-to-Insulin Ratio for use in determining insulin dosing during another time interval.
25
94. The method of Claim 75, wherein the version whose input is in the form of averages over a calendar period selects the appropriate algorithm to each time interval.

95. The method of Claims 94 and 3 wherein the method described in claim 3 is applied to time intervals containing small snacks.
96. The method of Claims 94 and 8 wherein the method described in claim 8 is applied to time intervals containing meals.
97. The method of Claim 94 and 3 wherein the method described in claim 3 is applied to time intervals designated as the source of Basal Rate for use in determining insulin dosing during another time interval.
98. The method of Claim 94 and 8 wherein the method described in claim 8 is applied to time intervals designated as the source of Carbohydrate-to-Insulin Ratio for use in determining insulin dosing during another time interval.
99. The method of Claim 94 and 16 wherein the method described in claim 16 is applied to time intervals containing After-Meal Corrective Insulin.
100. The method of Claim 75 wherein the Version of the invention whose input is in the form of averages over a calendar period for Multiple Daily Injection selects the appropriate algorithm to each time interval.
101. The method of Claims 100 and 5 wherein the method described in claim 5 is applied to time intervals containing small snacks.
102. The method of Claims 100 and 8 wherein the method of claim 8 is applied to time intervals containing meals.

103. The method of Claims 100 and 5 wherein the method described in claim 5 is applied to time intervals designated as the source of Basal Rate for use in determining insulin dosing during another time interval.
- 5 104. The method of Claim 100 and 8 wherein the method described in claim 8 is applied to time intervals designated as the source of Carbohydrate-to-Insulin Ratio for use in determining insulin dosing during another time interval.
- 10 105. The method of Claim 3 wherein the Multiple Days' Data version of the invention for Pumps selects the method described in Claim 3 to all the time intervals.
- 15 106. The method of calculating Basal Insulin in a give time interval as a Feedback Factor times the Corrective Insulin to be administered at the end of a given time interval and calculating the Meal Insulin for the time interval as the quantity (one minus the Feedback Factor) times the Corrective Insulin for the interval.
- 20 107. The method of Claim 36 wherein the constant is chosen for optimum speed of convergence to a Target Basal Insulin-to-Total Ratio.
- 25 108. The method of claim 8, further including determining a new carbohydrate-to-insulin ratio by dividing the grams of carbohydrates ingested during the time interval by the new Meal Insulin for the given time interval.
109. The method of claim 108, wherein the grams of carbohydrates ingested are determined by multiplying a carbohydrate-to-insulin ratio by a Meal Insulin dosage for the given time interval of a previous day.
110. The method of claim 109, wherein the given time interval constitutes a whole day.

111. The method of claim 110, wherein the given time interval constitutes a time interval amounting to less than a whole day.

112. The method of claim 8, wherein the sum of Meal Insulin and a corrective after-meal
5 insulin dosage is used in place of Meal Insulin.

113. The method of claim 112, wherein a feedback mechanism is used to regulate the relative proportions of the day's totals of Basal Insulin and Meal Insulin as part of the Prescription Insulin.
10

114. The method of claim 113, wherein the feedback mechanism is a factor representing the day's change in Basal Insulin divided by the day's change in Prescription Insulin.

115. The method of claim 114, wherein the feedback factor is calculated as:
15
$$BoTFbk(d) = BoT(d) + Kfbk * (BoTTgt - BoT(d)) * sign(deRxInsl).$$

116. The method of claim 8, including calculating a corrective insulin dosage for the given time interval based on the difference of averaged blood glucose measurements taken at or near a specified time over a plurality of days and a target blood glucose level
20 divided by a correction factor.

117. The method of claim 116, wherein the change to Prescription Insulin is determined as a number less the corrective insulin dosage for the time interval.

25 118. The method of claim 117, wherein the change to Prescription Insulin is a fraction of the corrective insulin for the given time interval equal to a multiplying factor times the corrective insulin for the time interval.

119. The method of claim 118, wherein the multiplying factor is a number that provides a response time for decreasing the amount of correction over a selected period of time for the correction.

- 5 120. The method of claim 119, wherein the multiplying factor is determined as:
one minus (the remaining percent of original error allowed at the end of the response
time) raised to the power (one divided by the number of days in the response time).

121. The method of claim 117, wherein the value of the change in total day's
10 Prescription Insulin is divided by the total day's corrective insulin to obtain the
multiplying factor.

122. (omitted)

- 15 123. The method of claim 121, wherein the change to Prescription Insulin applied is
limited to a maximum change value based on a set fraction of the sum of the day's total
corrective insulin.

124. The method of claim 117, wherein the change to Prescription Insulin is limited to a
20 maximum change value based on a set fraction of the corrective insulin determined at the
end of a given time interval.

125. The method of claim 121, wherein the change to Prescription Insulin is
automatically adjusted based on a percent standard deviation of a patient's blood glucose
25 in a recent calendar period compared to the mean percent standard deviation of a
population sample, and wherein if the patient's standard deviation is high relative to the
mean standard deviation of the population sample, then less change in the Prescription
Insulin is employed than the change determined.

126. The method of claim 125, wherein the change in Prescription Insulin equals a fraction multiplier times the maximum change determined.

127. The method of claim 126, wherein the multiplier is determined as follows: if the patient's percent standard deviation of blood glucose measurements is less than the mean of the population of the population percent standard deviations plus one standard deviation of the population percent standard deviations, then the value of the multiplier is one; if the patient's percent standard deviation of blood glucose measurements is between one and two percent standard deviations of the population standard deviation greater than the mean of the population percent standard deviation, then the multiplier is set to ramp linearly downwardly until it reaches zero at the upper bound of this interval; and if the patient's standard deviation of blood glucose measurements is greater than this, then the multiplier is set to zero, allowing no change in Prescription Insulin.

128. The method of claim 16, including calculating a corrective insulin dosage for the given time interval based on the difference of averaged blood glucose measurements taken at or near a specified time over a plurality of days and a target blood glucose level divided by a correction factor.

129. The method of Claim 8 of automatically estimating the change in Total Day's Basal as having the absolute value of the minimum of the absolute values of the following: (change in total day's Prescription Insulin) and (a target Basal Insulin minus the current Basal Insulin), the resulting minimum value being multiplied times the sign of the latter quantity.